



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/031,862	02/27/98	BUSSELL	L

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HM42/0814

EXAMINER
SPIVACK, P

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/14/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/031,862**

Applicant(s)  
**Bussell**

Examiner  
**Phyllis G. Spivack**

Group Art Unit  
**1614**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-3 \_\_\_\_\_ is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3 \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's Information Disclosure Statement filed February 27, 1998, paper No. 2, is acknowledged and the references have been reviewed. The cited references are supposed to be included with the filing of Form PTO-1449.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The parenthetical subject matter in claims 1 and 3 renders the claims vague and indefinite. It is unclear whether or not the parenthetical information is to be considered a claim limitation. It is suggested both the dosage range contemplated of the fluoroquinolone antibiotic in claim 1 and the weight percentage range of acetone in claim 3 are recited.

As a method of use claim, claim 1 requires an active step. For example, after "skin conditions" in line 1, Applicant may consider the insertion of -- comprising administering --.

Markush language is never open-ended. The recitation in claim 2, line 2, "but is not limited to" is improper.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antimicrobial activity, does not reasonably provide enablement for all skin conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The skilled artisan in dermatology, following a review of the present specification,

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would not be motivated to treat other skin conditions as, for example, atopic dermatitis or squamous cell carcinoma of the skin.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al., U.S. Patent No. 5,401,741, in view of Remington's Pharmaceutical Sciences.

The prior art discloses various topical preparations comprising a fluoroquinolone antibiotic in the treatment of microbial infections. Specifically, Sato teaches the topical administration of the fluoroquinolone antibiotic ofloxacin for treating otopathy. The claims differ in that Sato fails to disclose a pharmaceutical composition comprising a fluoroquinolone wherein both an alcohol and acetone are included. However, Remington teaches the utility of both acetone and alcohol as extremely commonly used solvents in pharmacy. Thus one skilled in the art would have been motivated to prepare a pharmaceutical composition comprising a fluoroquinolone antibiotic in which an alcohol and acetone were used as solvents. Such would have been obvious in the absence of evidence to the contrary because alcohol and acetone would have reasonably provided an optimum solvent system in pharmaceutical compositions comprising fluoroquinolones.

No claim is allowed.

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Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

August 13, 1998

*Phyllis Spivack*

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**